

**K180127 TCAT (R) THA Instrument Tray Set**Mar 15, 2019  
422 days to decisionK180127 · Product code: **KCT** · General Hospital  
Source: <https://www.510kdatabase.net/k180127/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (KCT)
Date received	Jan 17, 2018
Decision date	Mar 15, 2019
Days to decision	422 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>THINK Surgical, Inc.</b>
Location	Fremont, CA, US
Contact	John Hahn
Website	<a href="https://www.thinksurgical.com">https://www.thinksurgical.com</a>
510(k) history	22 submissions · 22 cleared · 2015-2026

THINK Surgical, Inc. is an innovator in orthopedic surgical robotics based in Fremont, California. The company develops miniature robotic systems that assist surgeons in performing joint replacement procedures. THINK Surgical has received FDA 510(k) clearances from total submissions since 2015. Orthopedic devices represent 86% of the company's regulatory portfolio. The company remains active, with its latest clearance in 2026. The company's core offering is the TMINI® Miniature Robotic System, a wireless robotic platform designed for total knee replacement. THINK Surgical...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Think Surgical, Incorporated</b>
Contact	George J. Prendergast

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k180127/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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